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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/511,023 | 10/08/2004 | Lars I. E. Oddsson | BU-082XX | 8760 |
| 207 | 7590 | 11/25/2009 | EXAMINER | |
| WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109 | | | | SMITH, FANGEMONIQUE A |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/511,023 | ODDSSON ET AL. | |
| | Examiner | Art Unit | |
| | Fangemonique Smith | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 July 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-10, 15-38, 71 and 72 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 2-10, 15-38, 71 and 72 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on July 6, 2009. Examiner acknowledges the amendment of claims 2-10, 15-21, 25-27 and 30-38; the cancellation of claims 11-14, 22-24, 28, 29 and 30-70; and the addition of new claims 71 and 72. Claims 2-10, 15-21, 25-27, 30-38, 71 and 72 are pending.

Claim Objections

2. Claims 5-10, 21, 36 are objected to because of the following informalities:
- a. At lines 1 and 2 of claim 5 it is suggested to modify the limitation “said layer with said plurality of sensors are mounted in a shoe” to read -- said layer with said plurality of sensors is mounted in a shoe --.
 - b. At lines 1 and 2 of claim 6 it is suggested to modify the limitation “said layer with said plurality of sensors are mounted in a stocking” to read -- said layer with said plurality of sensors is mounted in a stocking --.
 - c. At lines 1 and 2 of claim 7 it is suggested to modify the limitation “said layer with said plurality of sensors are mounted in a sandal” to read -- said layer with said plurality of sensors is mounted in a sandal --.
 - d. At lines 1 and 2 of claim 8 it is suggested to modify the limitation “said layer with said plurality of sensors are insertable into a shoe” to read -- said layer with said plurality of sensors is insertable into in a shoe --.

- e. At lines 1 and 2 of claim 9 it is suggested to modify the limitation "said layer with said plurality of sensors are insertable into a stocking" to read -- said layer with said plurality of sensors is insertable into in a stocking --.
- f. At lines 1 and 2 of claim 10 it is suggested to modify the limitation "said layer with said plurality of sensors are insertable into a sandal" to read -- said layer with said plurality of sensors is insertable into in a sandal --.
- g. At lines 2 and 3 of claim 21, Examiner suggests to modify the limitation "adapted to be implantable into said user's skin" to read -- adapted to be implanted into said user's skin --.
- h. At lines 2 and 3 of claim 36, it is suggested to modify the limitation "said balance control signal" to read -- said balance control signals -- to maintain consistency within claim language.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 2-4, 15-17, 19, 20, 34, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Claims 2-4 recite the limitation "said detected magnitude of forces" in lines 2 and 3. There is no prior mention of a detected magnitude of forces in claims 2-4 or in any claim from

which claims 2-4 depend. Therefore, there is insufficient antecedent basis for this limitation in the claim.

6. Claim 15 recites the limitation "said at least one balance information signal" in line 3.

There is no prior mention of an at least one balance information signal in claim 15 or in any claim from which claim 15 depends. Therefore, there is insufficient antecedent basis for this limitation in the claim.

7. Claim 16 recites the limitation "a sole" in line 7. There is a sole of said user's foot also disclosed in lines 4 and 5 of claim 16. It is unclear whether the limitation is referring to the same sole previously disclosed or if the limitation intends to introduce another sole, rendering the claim indefinite.

8. Claim 17 recites the limitation "said at least one balance information signal" in line 3.

There is no prior mention of an at least one balance information signal in claim 17 or in any claim from which claim 17 depends. Therefore, there is insufficient antecedent basis for this limitation in the claim.

9. Claim 19 recites the limitation "a plurality of stimulators" in line 7. There is an array of a plurality of stimulators disclosed in line 19 of claim 71, a claim from which claim 19 depends. It is unclear whether the limitation is referring to the array of plurality of stimulators previously disclosed in claim 71 or if the limitation intends to introduce another plurality of stimulators, rendering the claim indefinite.

10. Claim 19 recites the limitation "an array of stimulators" in lines 7 and 8. There is an array of a plurality of stimulators disclosed in line 19 of claim 71, a claim from which claim 19 depends. It is unclear whether the limitation is referring to the array of plurality of stimulators

previously disclosed in claim 71 or if the limitation intends to introduce another array of stimulators, rendering the claim indefinite.

11. Claim 20 recites the limitation "an array of stimulators" in line 2. There is an array of a plurality of stimulators disclosed in line 19 of claim 71, a claim from which claim 20 depends. It is unclear whether the limitation is referring to the array of plurality of stimulators previously disclosed in claim 71 or if the limitation intends to introduce another array of stimulators, rendering the claim indefinite.

12. Claim 34 recites the limitation "an array of stimulators" in lines 2 and 3. There is an array of a plurality of stimulators disclosed in line 19 of claim 71, a claim from which claim 34 depends. It is unclear whether the limitation is referring to the array of plurality of stimulators previously disclosed in claim 71 or if the limitation intends to introduce another array of stimulators, rendering the claim indefinite.

13. Claim 37 recites the limitation "said stimulation control signals" in lines 9 and 10. There is no prior mention of a stimulation control signal in claim 37 or in any claim from which claim 37 depends. Therefore, there is insufficient antecedent basis for this limitation in the claim.

14. Claim 38 recites the limitation "said stimulation control signal" in lines 9 and 10. There is no prior mention of a stimulation control signal in claim 38 or in any claim from which claim 38 depends. Therefore, there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 2-4, 15-19, 21, 25-27, 30-37, 71 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland et al. (U.S. Patent Number 7,403,821) in view of Allum (U.S. Patent Number 6,063,046).

In regard to claims 2-4, 15-19, 21, 25-27, 30-37, 71 and 72, Haugland et al. disclose methods and apparatuses for detection of neural or muscular activity. The apparatus disclosed by Haugland et al. includes a sensing layer adapted for wearing under a user's foot during conditions of standing and gait (col. 14, lines 46-67). The device further includes the use of stimulation electrodes as an excitation means which provides signals regarding user force and position during use (col. 5, lines 5-67; col. 6, lines 1-21). The information from the sensors are transmitted to a remote location as feedback to the user. The combined sensing and stimulation device disclosed by Haugland et al. further includes a means for processing the signals gathered during gait (col. 7, lines 49-67; col. 8, lines 1-19). Although Haugland et al. disclose features of Applicant's invention as described, Haugland et al. do not specifically disclose the use of the information gathered to control balance. Allum discloses a method and apparatus for the diagnosis and rehabilitation of balance disorders. The Allum device (20) comprises a plurality of sensors located in the support surface of the device for detecting balance information. The sensors are configured for wearing by placement under at least one foot of the user (col. 4, lines 55-67; col. 5, lines 1-30). The sensors transduce a detected magnitude of forces applied to the sensors and transmit at least one balance information signal to a signal processing subsystem (24). The Allum device further converts the balance information into at least one stimulation control

signal. A feedback mechanism acts as a stimulator (38), which is responsive to said at least one stimulation control signal (col. 10, lines 23-42). The stimulator is attachable to a body surface part of the user. The sensors disclosed by Allum are sensitive to forces oriented perpendicular and parallel to said plurality of sensors. The signal processing subsystem of the Allum device is further operable to convert the collected balance information signals received from the plurality of sensors into an estimate of a magnitude of force applied to a sole of at least one foot of the user. The signal processing system also determines a magnitude of the resultant reaction force applied to a sole of at least one foot of the user. The system incorporates the stimulator signaling means of the device providing a visual, audio, tactile and electro-vestibular feedback to the user upon placing the stimulator signaling means proximate with at least one sensory neuron of said user (col. 10, lines 23-42). This feature allows a user to employ cognitive recognition and respond to the stimulation based on recognizing the signal. Allum discloses the device having at least one stimulator securable to the body of a user (col. 17, lines 29-47). Stimulators of the Allum device are also capable of being secured on the head of the user or implantable within the body of the user (col. 26, lines 54-67; col. 27, lines 1-35). The stimulators of the Allum system are responsive to received stimulation control signals and the stimulus amplitudes, frequencies, and locations are indicative of at least one parameter describing forces applied to a sole of said at least one foot (col. 3, lines 5-67; col. 4; col. 5, lines 1-30). Allum further discloses at least one sensor for transducing an angle between at least one foot and an ipsilateral lower leg of a user. The balance information gathered by the device is transmitted to a signal processing system for converting the balance information into at least one stimulation control signal. A feedback mechanism acts as a stimulator (38), which is responsive to said at least one stimulation control

signal (col. 10, lines 23-42). The stimulator is attachable to a body surface part of the user. The sensors disclosed by Allum are operable to determine angles between the foot of the user and the ipsilateral lower leg of the user projected on a coronal or sagittal plane. The signal processing system of the Allum device determines a magnitude of an angle between at least one foot and the ipsilateral leg of the user. The system incorporates the stimulator signaling means of the device providing a visual, audio, tactile and electro-vestibular feedback to the user upon placing the stimulator signaling means proximate with at least one sensory neuron of said user (col. 10, lines 23-42). This feature allows a user to employ cognitive recognition and respond to the stimulation based on recognizing the signal. Allum discloses the device having at least one stimulator removably affixed to the body of the user (col. 7, lines 29-47). Stimulators of the Allum device are also capable of being secured on the head, arm or trunk of the user, or implantable within the body of the user (col. 26, lines 54-67; col. 27, lines 1-35). The stimulation control signals of the Allum device further encode time derivatives of the magnitude of pressure and of the radial position and angular position of the center of pressure under the foot of the user (col. 5, lines 2-67; col. 15, lines 4-67; col. 16; col. 17, lines 1-40). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify an apparatus for detection of neural or muscular activity, similar to that disclosed by Haugland et al., to include balance feedback, similar to that disclosed by Allum, to provide a way to determine balance information during gait techniques.

17. Claims 5-10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland et al. (U.S. Patent Number 7,403,821) in view of Allum (U.S. Patent Number 6,174,294) and in view of Crabb et al. (U.S. Patent Number 6,174,294).

In regard to claims 5-10 and 20, the combined references of Haugland et al. and Allum disclose the features of the Applicant's invention as described above. The combined references do not disclose the sensors being insertable into another device other than the platform. Crabb et al. disclose a limb load monitor, which provides feedback to a patient or user when a preselected force load is met or exceeded on the foot of the user. The plurality of sensors of the Crabb et al. device can be attached to a shoe or a stocking of a user. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a method and apparatus for the diagnosis and rehabilitation of balance disorders, similar to that disclosed by the combined references of Haugland et al. and Allum, to include at least one sensor which can be attached to a shoe or a stocking of a user, similar to that disclosed by Crabb et al., to provide a mechanism which potentially improves the connection between the sensors and the user while increasing the utility of the device.

Response to Arguments

18. Applicant argues the Allum reference does not teach a device which comprises both a sensing system under the foot and a stimulator system on a user's skin area operative in response to foot pressure signals as modified by Applicant. Examiner submits, the Haugland et al. reference newly presented in the rejection above discloses this feature of having both a sensing system under the foot and a stimulator system on a user's skin area operative in response to foot pressure signals to allow the wearer to regain balance during both standing and gait as claimed by Applicant. Applicant's arguments filed have been fully considered but they are moot in view of newly presented rejection. The rejection stands.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736